

which the article was intended and for which it was offered orally by the consignee to prospective purchasers.

DISPOSITION: 9-12-58. Default—destruction.

**5405. Oza Compound.** (F. D. C. No. 39849. S. No. 59-960 M.)

QUANTITY: 15 cases, 4 1-gal. jugs each, at Tampico, Ill.

SHIPPED: 11-28-56, from Fort Wayne, Ind., by Oza Compound Products.

LABEL IN PART: (Jug) "OZA \* \* \* Formula: Active Ingredients: Alum, Oak Bark, Rosin, Sodium Benzoate Oza Compound \* \* \* Use as a general tonic \* \* \* Directions: Children, up to 5 years, 1 tablespoonful, 5 to 10 years, 2 tablespoonsful, 10 to 15 years, 3 tablespoonsful. Adults, 4 tablespoonsful, after each meal."

LIBELED: 1-29-57, N. Dist. Ill.

CHARGE: 502 (a)—when shipped, the label of the article bore the statement "Use as a general tonic," which statement was false and misleading since the article was not a tonic; and 502 (f) (1)—the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended, and, because of its unscientific formula, it was not feasible to devise directions under which the layman could use the article to accomplish the purposes for which it was intended.

DISPOSITION: Willard Smith, t/a Oza Compound Products, appeared as claimant; and, on 3-15-57, upon stipulation of the parties, an order was entered directing that the case be transferred to the Southern District of Indiana. Interrogatories were served upon, and answered by, the claimant.

On 5-8-58, a consent decree of condemnation was entered; and, on 5-14-58, the article was ordered destroyed.

**5406. Ovacide.** (F. D. C. No. 40221. S. No. 66-334 M.)

QUANTITY: 17 6-oz. jars and 2 12-oz. jars and 1 drum containing 20 lbs. at Oakland, Calif.

SHIPPED: 2-22-56, from Portland, Oreg.

LABEL IN PART: (Jar) "Ovacide \* \* \* Antiseptic Powder."

LIBELED: 5-24-57, N. Dist. Calif.

CHARGE: 502 (a)—while held for sale, the name "Ovacide" and certain statements on the jar label represented and suggested that the article was antiseptic under conditions of use and was an adequate and effective treatment for all vaginal infections and inflamed catarrhal conditions of the mucous membranes, which name and statements were false and misleading since the article was not antiseptic under conditions of use and was not an adequate and effective treatment for the conditions represented; and 502 (f) (1)—the labeling of the article failed to bear adequate directions for use since the directions failed to specify that the article should not be used more than twice weekly for cleansing purposes only, unless otherwise directed by a physician.

DISPOSITION: 6-11-57. Default—destruction.

**5407. Head harness device.** (F. D. C. No. 40214. S. No. 72-962 M.)

QUANTITY: 15 devices at Salt Lake City, Utah.

SHIPPED: 3-27-57, from Idaho Falls, Idaho, by Clifford Thiede.

LABEL IN PART: "Thiede's Stretch-To-Health Head Harness Spine Normalizer Patent Applied For Serial No. D-27615 Manufactured and designed by Cliff Thiede 250 Shelley Street Phone 4293 Idaho Falls, Idaho."

ACCOMPANYING LABELING: Pamphlets entitled "Well I'll Be Hanged! Stretch Your Spine For Health."

RESULTS OF INVESTIGATION: The device consisted of chains, a doorway hanger, and a head harness for suspending the head.

LIBELED: 6-12-57, Dist. Utah.

CHARGE: 502 (a)—when shipped, the designation "Thiede's Stretch-To-Health Head Harness" and the labeling of the devices contained false and misleading representations that the devices were an adequate and effective treatment for normalizing the spine muscles, spasm, osteoarthritis, disc degeneration, herniated disc or disc protrusion, neuritis, headaches (migraine), nervous disorders, premature aging, poor circulation, poor elimination of waste material, decreased body functions, chronic strain, thinning of the vertebral discs, back and neck troubles, serious injury and malfunctioning of the organs of the body, and promoting and maintaining health; and 502 (f) (1)—the devices should be restricted to sale only on prescription since they were devices, which because of any potentiality for harmful effect, or the method of their use, or the collateral measures necessary to their use, were not safe except under the supervision of a practitioner licensed by law to direct the use of such devices, and hence for which "adequate directions for use" could not be prepared; and their labels failed to bear the statement "Caution: Federal law restricts this device to sale by or on the order of a ———, (the blank to be filled in by the professional designation of a properly licensed member of a professional group)."

DISPOSITION: 8-23-57. Consent—claimed by Clifford Thiede and relabeled.

#### DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS\*

5408. Digitoxin powder and digitoxin tablets. (F. D. C. No. 40157. S. Nos. 60-319/20 M.)

QUANTITY: 1 25-gram btl. of *digitoxin powder* and 69 1,000-tablet btl. of *digitoxin tablets* at Detroit, Mich.

SHIPPED: 11-27-56, from New York, N. Y., by European Chemical Co., Inc.

LABEL IN PART: (Btl.) "Digitoxin U. S. P. For Manufacturing Use Only \* \* \* Net 25 gms. European Chemical Co., Inc., New York, N. Y." and "Digitoxin, Mallard, 1000 tablets, White Round \* \* \* Mallard, Inc., Detroit, Mich."

RESULTS OF INVESTIGATION: The *digitoxin tablets* were prepared by the consignee using a portion of the bulk *digitoxin powder*.

Examination showed that the powder contained not more than 83.5 percent of digitoxin and that the tablets contained not more than 0.162 milligrams of digitoxin per tablet.

LIBELED: 4-23-57, E. Dist. Mich.

CHARGE: 501 (b)—the *digitoxin powder* and the *digitoxin tablets* purported to be a drug, "Digitoxin," the name of which is recognized in the United States Pharmacopeia, an official compendium; and, when the powder was shipped and while the tablets were held for sale, the strength of the articles differed

\*See also Nos. 5401, 5402.